

# EXHIBIT F

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA

In Re:  
Bair Hugger Forced Air Warming  
Products Liability Litigation

This Document Relates To:

## All Actions

MDL No.

15-2666 (JNE/FLM)

VIDEOTAPED DEPOSITION

OF

CHRISTOPHER NACHTSHEIM

Minneapolis, Minnesota

Tuesday, November 29, 2016

Reported by:

Amy L. Larson, RPR

Job No. 113495

1 NACHTSHEIM  
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18 ALSO PRESENT: Kraig Hildahl, Videographer

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## PROCEEDINGS

1 THE VIDEOGRAPHER: This is the  
2 Start of tape labeled number 1 of the  
3 videotaped deposition of Christopher  
4 Nachtsheim in the matter of In Re: Bair  
5 Hugger Forced Air Warming Products Liability  
6 Litigation in the U.S. District Court for the  
7 District of Minnesota, Case Number 15-2666  
8 (JNE/FLM).

9 This deposition is being held at the  
10 Faegre Baker law firm in Minneapolis,  
11 Minnesota, on November 29th, 2016. We are  
12 going on the record at 9:11 a.m. My name is  
13 Kraig Hildahl, I'm the legal video specialist  
14 from TSG Reporting. The court reporter is  
15 Amy Larson also in association with

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NACHTSHEIM

TSG Reporting.  
Will counsel please introduce  
themselves for the record

MS. GARCIA: Christin Garcia, counsel for defendants 3M and Arizant.

MS. LEWIS: Deborah Lewis also  
counsel for defendants 3M and Arizant.

MR. SACCHET: Michael Sacchet for plaintiffs.

THE VIDEOGRAPHER: Will the court reporter please swear in the witness and then we can proceed.

CHRISTOPHER NACHTSHEIM,  
a witness in the above-entitled action,  
after having been first duly sworn, was  
deposed and says as follows:

## EXAMINATION

BY MS. GARCIA:

Q. Hello, Professor Nachtsheim.

A. Hello.

Q. Thank you for coming here today. Could you start by, for the record, just providing your

## NACHTSHEIM

full name and spell your last name and let us know your address.

A. Christopher John Nachtsheim. And it's N as in north, A-C-H-T, S as in Sam, H-E-I-M. Address is 1789 Summit Avenue, St. Paul, Minnesota 55105.

Q. Thank you. Have you ever been deposed before?

A. Yes.

Q. Okay. The one rule of deposition I just want to reinforce today is if you have any difficulty understanding -- well, if you don't understand my question, if you would like me to clarify something, will you please let me know that?

A. Uh-huh. Yes.

Q. Yes?

A. Yes.

Q. There's rule number 2.

A. That's rule number 2, I knew that.

Q. You will need to say things out loud so that we can get an accurate transcription of the record in writing where your head movements can't be taken down, and then we will try not

<p>1 NACHTSHEIM 2 object to the form of the question. 3 THE WITNESS: I -- I read this -- 4 MR. SACCHET: I can walk through 5 it slower. 6 THE WITNESS: Well, I read this to 7 say that in March 2009 there was a change to 8 the combination of the two drugs you've 9 pronounced, and I don't believe there were 10 any changes until the end of the study. 11 MR. SACCHET: Okay. 12 BY MR. SACCHET: 13 Q. So -- so we're clear, there was a period in 14 which Gentamycin was applied to some 15 forced-air warming patients, and then the 16 antibiotic changed to a combination of 17 Gentamycin and Teicoplanin that applied to 18 some forced-air warming patients and all of 19 the conductive fabric warming patients, 20 correct? 21 A. Correct. 22 Q. Assuming the change in antibiotic did not 23 affect infection rates between warming 24 devices, would you still consider the 25 antibiotic a confounding variable?</p>	<p>1 NACHTSHEIM 2 MS. GARCIA: Object to the form of 3 the question. 4 THE WITNESS: I'm going to assume 5 that it has -- the change had no effect? 6 BY MR. SACCHET: 7 Q. Yeah, assume that the antibiotic had no 8 effect on the infection rate. Would it still 9 be a confounding variable? 10 MS. GARCIA: Object to the form of 11 the question. 12 THE WITNESS: I don't think it 13 would be -- I don't think it would be 14 considered a confounding variable. I'm 15 trying to think of how else it might have an 16 impact, if it's not having an effect. I 17 guess it -- no, I don't think it would be, 18 yeah. 19 BY MR. SACCHET: 20 Q. One way that we could control for the -- let 21 me strike that. 22 In order to determine whether the 23 antibiotic had an effect on infection rates, 24 we could control for the warming device -- 25 A. Yes.</p>
<p>1 NACHTSHEIM 2 Q. -- and evaluate whether infection rates 3 between the changed antibiotic stayed the 4 same or went up or down -- 5 A. Correct. 6 Q. -- with that control device, correct? 7 A. (Nods head.) 8 MS. GARCIA: I'm going to object 9 to the form of the question. 10 BY MR. SACCHET: 11 Q. Did you understand it? 12 A. Yes. 13 Q. If infection rates between the two groups 14 were similar, that would tend to show that 15 the antibiotic was not a confounding factor? 16 A. Correct. 17 MS. GARCIA: Object to the form of 18 the question. 19 BY MR. SACCHET: 20 Q. Assume that Mr. Albrecht, who you previously 21 mentioned was an expert in statistics and you 22 had full confidence in his ability to analyze 23 data presented in this article, informed you 24 that he found a 2.8 percent infection rate in 25 those who received Gentamycin, a single drug,</p>	<p>1 NACHTSHEIM 2 but 3.1 percent of patients who received the 3 combination of antibiotics, but also 4 forced-air warming patients, with a nearly 5 identical infection rate, would you determine 6 that the antibiotic was a confounding factor? 7 MS. GARCIA: Object to the form of 8 the question. 9 THE WITNESS: That would be strong 10 evidence that it was not a confounding 11 factor. 12 MR. SACCHET: Let's mark this. 13 (Whereupon, Exhibit 27 was 14 marked for identification.) 15 BY MR. SACCHET: 16 Q. So just to be clear, if we look at this table 17 that's presented here, we can see in the 18 first line it presents antibiotic protocol 1 19 versus 2 for FAW, does it not? 20 A. It does. 21 Q. Assume that protocol 1 is the singular 22 antibiotic, i.e. Gentamycin, and that 23 protocol 2 is the combination of Gentamycin 24 and Teicoplanin. 25 A. Uh-huh. Yes.</p>

<p>1 NACHTSHEIM</p> <p>2 Q. In this particular analysis, forced-air</p> <p>3 warming is held constant, correct?</p> <p>4 A. Correct.</p> <p>5 Q. And for forced air, protocol 1, the percent</p> <p>6 of patients developing infection was 2.8?</p> <p>7 A. Correct.</p> <p>8 Q. And for forced air, protocol 2, involving</p> <p>9 patients who received both Gentamycin and</p> <p>10 Teicoplanin, the infection rate was 3.1,</p> <p>11 correct?</p> <p>12 A. Correct.</p> <p>13 Q. And the p-value was 0.839, correct?</p> <p>14 A. That's what's reported here.</p> <p>15 Q. That's what's reported here. We could</p> <p>16 conclude, based on this data set of these</p> <p>17 numbers, that when the patient-warming device</p> <p>18 is held constant, that the change in</p> <p>19 antibiotic had no effect on infection rates,</p> <p>20 correct?</p> <p>21 MS. GARCIA: Object to the form of</p> <p>22 the question.</p> <p>23 THE WITNESS: Assuming there's</p> <p>24 sufficient power in those sample sizes,</p> <p>25 although they look fairly large to me, yes.</p>	<p>1 NACHTSHEIM</p> <p>2 BY MR. SACCHET:</p> <p>3 Q. The patient population for forced-air</p> <p>4 protocol 1 was 389 patients, correct?</p> <p>5 A. Correct.</p> <p>6 Q. And the patient population for those</p> <p>7 receiving the combination was 678, correct?</p> <p>8 A. Correct.</p> <p>9 Q. Those are fairly large patient populations,</p> <p>10 correct?</p> <p>11 A. Correct.</p> <p>12 MS. GARCIA: Object to the form of</p> <p>13 the question.</p> <p>14 BY MR. SACCHET:</p> <p>15 Q. Another way to determine whether the</p> <p>16 antibiotic was a confounding variable would</p> <p>17 be to control the antibiotic, but evaluate</p> <p>18 different infection rates between different</p> <p>19 forced-air -- or different warming devices,</p> <p>20 correct?</p> <p>21 A. Yes.</p> <p>22 MS. GARCIA: Object to the form of</p> <p>23 that question also.</p> <p>24 BY MR. SACCHET:</p> <p>25 Q. And if the infection rates were still higher</p>
<p>1 NACHTSHEIM</p> <p>2 among those who received forced-air warming</p> <p>3 compared to those who received conductive</p> <p>4 fabric warming, that would tend to show the</p> <p>5 antibiotic did not substantially affect</p> <p>6 infection rates, correct?</p> <p>7 A. Correct.</p> <p>8 MS. GARCIA: Object to the form of</p> <p>9 the question.</p> <p>10 BY MR. SACCHET:</p> <p>11 Q. And if that's true, the change in antibiotic</p> <p>12 would also not be a confounding factor,</p> <p>13 correct?</p> <p>14 A. Correct.</p> <p>15 MS. GARCIA: Object to the form of</p> <p>16 the question.</p> <p>17 BY MR. SACCHET:</p> <p>18 Q. If I could --</p> <p>19 MR. SACCHET: Could I ask your</p> <p>20 basis for the objection?</p> <p>21 MS. GARCIA: I'm sorry?</p> <p>22 MR. SACCHET: Could I ask your</p> <p>23 basis for the objection on form?</p> <p>24 MS. GARCIA: Yes. You keep using</p> <p>25 the word, "determine," and you keep using the</p>	<p>1 NACHTSHEIM</p> <p>2 word, "show," and you keep using the word,</p> <p>3 "establish," and I'm objecting to the form of</p> <p>4 the question based on those terms.</p> <p>5 MR. SACCHET: That's not going to</p> <p>6 pass muster in the court.</p> <p>7 BY MR. SACCHET:</p> <p>8 Q. As to the hypothetical I just presented, if</p> <p>9 you could turn your attention to the second</p> <p>10 line of the table.</p> <p>11 MS. GARCIA: I'm sorry, to just be</p> <p>12 complete with my form objection, it's also an</p> <p>13 incomplete hypothetical.</p> <p>14 MR. SACCHET: Fair enough.</p> <p>15 BY MR. SACCHET:</p> <p>16 Q. Antibiotic protocol 2 involved a combination</p> <p>17 have Gentamycin and Teicoplanin, correct?</p> <p>18 MS. GARCIA: Object to</p> <p>19 foundation --</p> <p>20 BY MR. SACCHET:</p> <p>21 Q. -- for the sake of --</p> <p>22 A. Yes.</p> <p>23 MS. GARCIA: Excuse me. Object to</p> <p>24 foundation for that.</p> <p>25 BY MR. SACCHET:</p>

<p>1 NACHTSHEIM</p> <p>2 Q. And the data here shows that 3.1 percent of</p> <p>3 patients who received forced-air warming in</p> <p>4 the combination antibiotic developed joint</p> <p>5 infections, correct?</p> <p>6 A. Correct.</p> <p>7 Q. Whereas, .9 percent of patients who received</p> <p>8 conductive fabric warming and the combination</p> <p>9 of antibiotics developed joint infections,</p> <p>10 correct?</p> <p>11 A. Correct.</p> <p>12 Q. By holding the antibiotic constant and</p> <p>13 discontinuing the use of forced-air warming,</p> <p>14 that resulted in a 71 percent decrease in</p> <p>15 joint infections, did it not?</p> <p>16 MS. GARCIA: Object to the form of</p> <p>17 the question.</p> <p>18 THE WITNESS: Yes, it did.</p> <p>19 BY MR. SACCHET:</p> <p>20 Q. That essentially matches the 73 percent</p> <p>21 decrease in infections that was noted in the</p> <p>22 McGovern article itself, does it not?</p> <p>23 A. Correct.</p> <p>24 MS. GARCIA: Object to the form of</p> <p>25 the question.</p>	<p>1 NACHTSHEIM</p> <p>2 BY MR. SACCHET:</p> <p>3 Q. And based on the p-value of .0008, which is</p> <p>4 far less than .05, you would determine that</p> <p>5 difference to be statistically significant,</p> <p>6 would you not?</p> <p>7 A. I would.</p> <p>8 Q. So whether we control for the device or</p> <p>9 control for the antibiotic, based on this</p> <p>10 data set in Exhibit 27, would you determine</p> <p>11 that the antibiotic was not a confounding</p> <p>12 factor?</p> <p>13 MS. GARCIA: Object to the form of</p> <p>14 the question, it's a lack of foundation, it's</p> <p>15 an incomplete hypothetical.</p> <p>16 THE WITNESS: This data certainly</p> <p>17 supports that hypothesis.</p> <p>18 BY MR. SACCHET:</p> <p>19 Q. And if it were not a confounding factor,</p> <p>20 would there be any reason to deselect</p> <p>21 patients from the population of 1,437</p> <p>22 accounted for in the McGovern study in order</p> <p>23 to exclude those who received a single</p> <p>24 antibiotic?</p> <p>25 A. No.</p>
<p>1 Page 340</p> <p>2 NACHTSHEIM</p> <p>3 MS. GARCIA: Object to the form of</p> <p>4 the question.</p> <p>5 BY MR. SACCHET:</p> <p>6 Q. And if we were to do that and reduce the</p> <p>7 population, let's say, from the 1,473, or 37,</p> <p>8 I've forgotten which number it is, down to a</p> <p>9 number of let's say 500 patients, there could</p> <p>10 be concern about the powering of that</p> <p>11 population?</p> <p>12 A. There could. There could be.</p> <p>13 Q. Another confounding factor that was discussed</p> <p>14 this afternoon was a change in the</p> <p>15 thromboprophylaxis protocol, correct?</p> <p>16 A. Yes. Can -- can you just remind me where</p> <p>17 that --</p> <p>18 Q. Yeah, if we could turn to page 1540.</p> <p>19 A. (Complies.)</p> <p>20 Q. If you look at the bottom of the first full</p> <p>21 paragraph in the left-hand column, it states</p> <p>22 the thromboprophylaxis regimen from</p> <p>23 July 2008 to the end of July 2009 was</p> <p>24 Tinzaparin.</p> <p>25 A. Uh-huh.</p> <p>Q. Then it says from August 2009 to February</p>	<p>1 Page 341</p> <p>2 NACHTSHEIM</p> <p>3 2010, Rivaroxaban, which I'll represent is</p> <p>4 otherwise known as Xarelto, was provided from</p> <p>5 day one, but in February 2010 to the end of</p> <p>6 this study, patients were reverted to</p> <p>7 Tinzaparin, correct?</p> <p>8 A. Yes.</p> <p>9 Q. Assuming the change in the prophylaxis did</p> <p>10 not affect infection rates during the time of</p> <p>11 this study, i.e., Exhibit 4, would you still</p> <p>12 consider it a confounding variable?</p> <p>13 A. No.</p> <p>14 MS. GARCIA: Object to the form of</p> <p>15 the question.</p> <p>16 (Whereupon, Exhibit 28 was</p> <p>17 marked for identification.)</p> <p>18 MS. GARCIA: What number are we</p> <p>19 on?</p> <p>20 MR. SACCHET: Twenty-eight, I</p> <p>21 believe.</p> <p>22 THE COURT REPORTER: Correct.</p> <p>23 MS. GARCIA: Thank you.</p> <p>24 BY MR. SACCHET:</p> <p>25 Q. Have you seen this document before,</p> <p>Professor?</p>

<p>1 NACHTSHEIM</p> <p>2 p-value was a statistically significant</p> <p>3 value, correct?</p> <p>4 A. Yes, correct.</p> <p>5 Q. So there were fewer wound complications as a</p> <p>6 result of the use of a low weight molecular</p> <p>7 heparin --</p> <p>8 A. Correct.</p> <p>9 Q. -- compared to Rivaroxaban, correct?</p> <p>10 A. Yeah, correct.</p> <p>11 MS. GARCIA: Object to the form of</p> <p>12 the question.</p> <p>13 BY MR. SACCHET:</p> <p>14 Q. However, the study notes that rates for RTT,</p> <p>15 which we established to be a return to</p> <p>16 theater for --</p> <p>17 A. Uh-huh.</p> <p>18 Q. -- infections, were not significantly</p> <p>19 different; do you see that?</p> <p>20 A. Correct. Yes, I do.</p> <p>21 Q. Assuming the truth -- well, let me back up.</p> <p>22 Would you also agree that the</p> <p>23 McGovern study, Exhibit --</p> <p>24 MS. GARCIA: Four.</p> <p>25 BY MR. SACCHET:</p>	<p>1 NACHTSHEIM</p> <p>2 Q. -- 4, evaluated joint infections?</p> <p>3 A. Yes.</p> <p>4 Q. It did not evaluate wound complications, did</p> <p>5 it?</p> <p>6 A. Correct, it did not.</p> <p>7 Q. Assuming the truth of this study, would you</p> <p>8 ultimately agree that the change in protocol</p> <p>9 from Tinzaparin, which is an LMWH, to</p> <p>10 Xarelto, otherwise known as Rivaroxaban, and</p> <p>11 then back to Tinzaparin, did not</p> <p>12 significantly affect the infection rate?</p> <p>13 MS. GARCIA: Object to the form of</p> <p>14 the question, to lack of foundation, and it's</p> <p>15 an incomplete hypothetical.</p> <p>16 THE WITNESS: Assuming the study</p> <p>17 was carefully done and generalizable, yes.</p> <p>18 BY MR. SACCHET:</p> <p>19 Q. And assuming the study was well done and</p> <p>20 generalizable, would you agree that the</p> <p>21 change in thromboprophylaxis noted in the</p> <p>22 McGovern study, Exhibit 4, did not confound</p> <p>23 the infection rates?</p> <p>24 MS. GARCIA: Object to the form of</p> <p>25 the question.</p>
<p>1 Page 348</p> <p>2 NACHTSHEIM</p> <p>3 THE WITNESS: Assuming -- yes.</p> <p>4 BY MR. SACCHET:</p> <p>5 Q. And would you also conclude that, assuming</p> <p>6 the truth of this study, it would be improper</p> <p>7 to deselect all of the patients who received</p> <p>8 Xarelto, otherwise known as Rivaroxaban, from</p> <p>9 the patient population if the</p> <p>10 thromboprophylaxis was not a confounding</p> <p>11 variable?</p> <p>12 MS. GARCIA: Object to the form of</p> <p>13 the question.</p> <p>14 THE WITNESS: It doesn't seem</p> <p>15 justified in -- on the basis of these</p> <p>16 results.</p> <p>17 BY MR. SACCHET:</p> <p>18 Q. And, in fact, when the coauthors of the</p> <p>19 McGovern study were in the process of</p> <p>20 publication, are you aware that at numerous</p> <p>21 times they sought to collect additional data</p> <p>22 in support of the study?</p> <p>23 A. I was not aware of that. I knew that -- I</p> <p>24 knew that they sought to run this study out</p> <p>25 in time.</p> <p>Q. Are you aware that when Mr. Albrecht and</p>	<p>1 Page 349</p> <p>2 NACHTSHEIM</p> <p>3 Dr. Reed collected additional data that went</p> <p>4 beyond January 2011 in the conductive fabric</p> <p>5 warming population, that the data still</p> <p>6 showed a significant decrease in infections</p> <p>7 when conductive fabric warming was used?</p> <p>8 A. I'm aware of that.</p> <p>9 Q. Assuming that --</p> <p>10 MS. GARCIA: Can we take a break</p> <p>11 shortly?</p> <p>12 MR. SACCHET: Yeah, give me two</p> <p>13 minutes.</p> <p>14 BY MR. SACCHET:</p> <p>15 Q. Assuming that neither the antibiotic nor the</p> <p>16 thromboprophylaxis protocol required control</p> <p>17 because they were not confounding factors as</p> <p>18 we discussed, you would be confident in the</p> <p>19 results of the observational study presented</p> <p>20 in the McGovern data?</p> <p>21 MS. GARCIA: Object to the form of</p> <p>22 the question.</p> <p>23 THE WITNESS: I'm confident that</p> <p>24 those weren't confounding factors, that those</p> <p>25 studies are well done. It doesn't rule out</p> <p>the potential for other confounding factors.</p>

<p style="text-align: right;">Page 350</p> <p>1                   NACHTSHEIM 2                   MR. SACCHET: Fair enough. 3   BY MR. SACCHET: 4   Q. And you continue to stand by the results of 5    the observational studies -- 6   A. Yes. 7   Q. -- in the McGovern publication? 8   A. I do. 9                   MR. SACCHET: Let's take a break. 10                  THE VIDEOGRAPHER: We're going off 11                  the record at 5:07 p.m. 12                  (Whereupon, a brief recess 13                  was taken.) 14                  THE VIDEOGRAPHER: This is video 15                  number 6 in the deposition of Christopher 16                  Nachtsheim. Today is November 29th, 2016. 17                  We're going back on the record at 5:18 p.m. 18   BY MR. SACCHET: 19   Q. Professor Nachtsheim, if we could turn to 20    Exhibit 5, which is the Belani study. 21   A. I have it. 22   Q. Great. And as to this study, your role was 23    to exclusively review the statistical portion 24    of this study, correct? 25   A. Correct.</p>	<p style="text-align: right;">Page 351</p> <p>1                   NACHTSHEIM 2                   Q. You had no involvement in the setup of the 3                  experiment? 4                  A. I did not. 5                  Q. You had no role in the execution of the 6                  physical experiment? 7                  A. I did not. 8                  Q. You had seen, whether by video or in person, 9                  disruption of laminar flow caused by the 10                 Bair Hugger before, correct? 11                 A. I had, yes. 12                 MS. GARCIA: I'm sorry, can I hear 13                 that question again? I was thinking and I 14                 did not hear the question. 15                 MR. SACCHET: Can you -- do you 16                 mind repeating it. 17                 (Whereupon, the last question 18                 was read by the court reporter.) 19                 MS. GARCIA: Object to the form of 20                 the question, asked and answered. 21   BY MR. SACCHET: 22   Q. So you were familiar with the possibility, 23    based on your personal experience, that the 24    Bair Hugger could disrupt laminar airflow, 25    correct?</p>
<p style="text-align: right;">Page 352</p> <p>1                   NACHTSHEIM 2                   MS. GARCIA: Object to the form of 3                  the question, misstates the record and lack 4                  of foundation. 5                   THE WITNESS: Correct. 6   BY MR. SACCHET: 7   Q. If we could turn to the third page of the 8    study. 9   A. (Complies.) 408? 10   Q. Yes. Do you see the header entitled, 11    "Statistical Analysis"?12   A. I do. 13   Q. And it reads, "A Poisson regression model for 14    overdispersed data was fit having the sum of 15    bubble counts for each experimental run," 16    paren, "ten pictures," end parens, "as the 17    response, and the factors identified in the 18    experimental design as predictors plus an 19    interaction term." Do you see that? 20   A. I do, yes. 21   Q. Did you determine that a Poisson regression 22    was the most appropriate statistical model to 23    employ because you were dealing with counts 24    data -- or data counts? 25   A. Yes.</p>	<p style="text-align: right;">Page 353</p> <p>1                   NACHTSHEIM 2                   MS. GARCIA: Object to the form of 3                  the question, previously asked and answered. 4   BY MR. SACCHET: 5   Q. And that Poisson regression was a better 6    model to use than, let's say, an ANOVA model? 7                 MS. GARCIA: Object to the form of 8                  the question, previously asked and answered. 9                 THE WITNESS: Yes. 10   BY MR. SACCHET: 11   Q. And if we could just turn our attention one 12    paragraph above that, it says, "For the 13    experimental design, a replicated and equals 14    to 2 by 3 full factorial design was used to 15    assess changes in bubble counts over the 16    surgical site," correct? 17   A. Correct. 18   Q. And what were the factors? 19   A. So the first factor is the anesthesia screen, 20    low grade/high grade, those are the two 21    levels, and then there were three 22    patient-warming devices, conductive fabric, 23    forced-air or no warming device, and that 24    would -- that was considered a control. 25   Q. Does Figure 3, directly above that paragraph,</p>